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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/677,630      | 10/03/2000  | Leon Forman          | 320-4(a)            | 5469             |

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EXAMINER

PALABRICA, RICARDO J

ART UNIT PAPER NUMBER

3641

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/677,630 | Applicant(s)<br>FORMAN, LEON |  |
|                              | Examiner<br>Rick Palabrica    | Art Unit<br>3641             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 18 is/are rejected.
- 7) ☒ Claim(s) 4 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 2/23/04, which included an amendment that directly revises claim 1, cancels claim 2, and adds new claims 17 and 18, has been entered. Of the two new claims, only claim 18 is directed to the elected invention. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 17 is withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP 821.03.

2. The Examiner agrees that the claim amendment overcomes the rejection based on the applied art, Miller (U.S. 3,816,785). However, the claimed invention still does not define over some other prior art, as discussed below.

Applicant's statement in the Remarks section of his amendment casting doubt on the operability of the Miller patent has no probative value because it is based on his opinion and not supported by corroborative evidence. Also, an

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issued patent, such as Miller's, shall be presumed valid, as per 35 U.S.C. 282, first sentence.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no support in the specification for the claim limitation of operating the neutron generator at 25 watts.

4. Claims 1, 3, 5-8, 10 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "close proximity with a tumor", which is a relative term that renders the claim indefinite. The term "close proximity" is not defined by the claim, the specification does not provide a standard for ascertaining the

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requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 3 is vague and indefinite for the reason given in section 3 above. The metes and bounds of the claims cannot be determined.

Claim 18 recites the limitation "said feed through accelerator" in line 2.

There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Objections***

5. Claims 4 and 9 are objected to because they are recited as dependent from a non-existing claim 2. (Note: The Examiner examines these claims based on the assumption that they depend from claim 1. See sections below).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-8, 10 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (U.S. 3,786,258) who discloses a closed system neutron generator tube for radiotherapy (e.g., see Abstract and Figs. 1-9). His apparatus includes an electron bombardment ion source (see column 7, lines 30+).

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Applicant's claim language reads on Schmidt's generator as follows: a) "repeller" reads on cathode 2 that can repel electrons (both the cathode and electrons are negatively charged); b) "anode defining an exit slit" reads on anode 1 having an aperture ("slit") facing target 3, as shown in Fig. 1; c) "focusing aperture" reads on aperture presented by acceleration electrodes 5 to said exit slit; d) "hollow needle sealed on one end" reads on the sealed, tapered (i.e., needle form) portion of target electrode 120 (see Fig. 8); e) "an occluded reaction target mounted within said hollow needle substantially towards said sealed end of said needle" reads on the part of target 120 at the sealed end facing element 126 (see Fig. 8); g) "steering/rasterizing means" reads on magnet coils 32, 33 that create the coaxial magnetic field (see column 1, lines 48+); h) "filament" reads on nickel tube 105 that heats up when fed by current from supply 114 (see column 10, lines 35+)..

As to the limitation in claim 1 regarding the exit slit and focusing apertures each being at least 3 mm in width, Schmidt inherently meets this limitation based on Fig. 1 and considering the actual sizes of the parts that constitute his apparatus. A 3mm width is very thin and is equivalent to the thickness of several tens of sheets of paper. Even if one takes Fig. 1 as an actual representation of the apparatus, which is not the case, the slits have widths of more than 3mm.

As to claim 3, the limitation regarding the neutron source strength and power is a statement of intended or desired use that does not patentably distinguish the claimed invention from Schmidt.

As to claim 4, the limitation regarding the current and energy of the ion beam is also a statement of intended or desired use that does not patentably distinguish the claimed invention from Schmidt. Note, however, that Schmidt is capable of meeting this limitation (see column 8, lines 1+, and column 1, lines 20+).

As to claim 8, the limitation on the operation of the steering means is again a statement of intended or desired use. Schmidt has the capability to meet this limitation because his magnet coils 32 and 33 are fed by a low voltage supply (see column 11, lines 13+).

As to claim 10, Schmidt's apparatus generates 14 MeV neutrons (see Abstract).

As to claims 7 and 18, the non-structural limitations in the claims are statements of intended or desired use.

The claims are replete with statements that are either essentially method limitations or statements of intended or desired use. For example, "for treating tumors", "for extracting ions on an opposite end of said ionization chamber", "delivering on the order of  $\geq 10^8$  neutrons per second operating at 25 watts", "deliver an ion beam of a few tens of microamperes to said target operating at 75-500 keV", "is sustained at ground potential", etc. These clauses, as well as other statements of intended use do not serve to patently distinguish the claimed structure over that of the reference, as long as the structure of the cited references is capable of performing the intended use. See MPEP 2111-2115.

See also MPEP 2114 that states:

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A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531.

[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528.

As set forth in MPEP 2115, a recitation in a claim to the material or article worked upon does not serve to limit an apparatus claim.

The device in the cited reference is capable of being used in the same manner and for the intended or desired use as the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt who discloses the applicant's claims except for the needle dimension and configuration of the needle with respect to the exit slit. The claim is obvious over Schmidt because of MPEP 2144.04, Section IV.A, which states,

"[W]here the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed



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relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.”

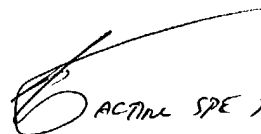
Alternatively, the limitation in the claim is a matter of optimization within prior art conditions or through routine experimentation (see MPEP 2144.05 II.A).

**Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 703-306-5756. The examiner can normally be reached on 7:00-4:30, Mon-Fri; 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Carone can be reached on 703-306-4198. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 ACTING SPE 3641

RJP  
June 29, 2004